

S.N. 09/510,937

small first diameter for insertion into a vascular conduit to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polyethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons again due to its flexibility, thinness, strength and lubricious materials.

III. RESTRICTION REQUIREMENT

The Examiner states that original claims 1-9 and newly submitted claims 10-20 cover composites having node and fibril structure in which porous fluoropolymers have nonporous fluoropolymer layers thereon, while newly added claims 21-28 relate to a different invention covering composites of porous fluoropolymer layers with nonporous fluoropolymer layers thereon.

Applicants respectfully disagree with the Examiner's conclusion that claims 21-28 are directed to a different class, as follows.

First, while many dependent claims are limited to a non-porous fluoropolymer layer applied over the porous fluoropolymer layer (wherein the porous fluoropolymer is required by all of the claims to be porous expanded PTFE), the non-porous layer of claim 1 is required only to be non-porous and is not limited to a non-porous fluoropolymer. Claim 21 differs from claim 1 primarily in that claim 21 simply requires that the inflatable balloon comprises porous expanded PTFE and does not require the additional layer of the non-porous coating required in claim 1.

It appears that the Examiner's conclusion is based on the language in claim 1 specifying that the porous expanded PTFE has a microstructure of nodes interconnected by fibrils, while that language is not explicitly present in claim 21. However, it is pointed out that claim 21 states that the inflatable balloon is formed from porous expanded PTFE. The "expanded" limitation necessarily results in the microstructure of nodes interconnected by fibrils, please see US 3,593,566 to Gore which describes this material (usually referred to in the vernacular as "ePTFE") and the "expansion" that results in the porous microstructure of nodes and fibrils.

Accordingly, applicants elect claims 1-20 for prosecution at this time, with traverse. Reconsideration of the restriction requirement is respectfully requested.

S.N. 09/510,937

IV. REJECTION OF CLAIMS 1-20 UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING OVER CLAIM 5 OF US 5,972,441 TO CAMPBELL et al. IN VIEW OF BUCK et al., US 4,925,710 AND THE PRESENT SPECIFICATION AT PAGE 2, LINES 6+.

Applicants submit herewith a terminal disclaimer with regard to US 5,972,441. It is pointed out that a terminal disclaimer was submitted previously in the present application (on Oct. 5, 2000, relating to other patents in the same family as the '441 patent).

Applicants would also note the following with regard to the Examiner's arguments relating to the relevance of the cited references.

Buck et al. teach the manufacture of wire insulation and tubes which might be used for automotive cables or medical catheters. While a tubing as taught by Buck et al. may be suitable as a catheter tube, the very characteristics that make it useful as a catheter (stiffness and rigidity adequate to allow it to be pushed through body lumens without collapse) would preclude the flexibility necessary for its use in the construction of an inflatable balloon. The present material, as configured for use as an inflatable balloon, has a high degree of flexibility (e.g., allowing it to be folded to a small size for insertion into the vasculature, allowing it to be readily inflated by introduction of an inflation medium such as saline and allowing it to collapse to a small and still-flexible form following deflation which would allow for ease of withdrawal from a body lumen).

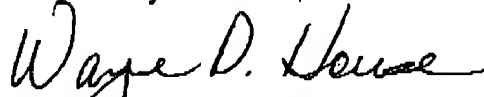
Likewise, the tubing of Buck et al. is inherently impermeable in all layers, there is no suggestion to use a permeable material such as ePTFE that is highly flexible.

Further, claim 5 of the '441 patent is directed to a sleeve for use over a catheter balloon and is not directed to a balloon per se.

In summary, there is nothing in these references, alone or in combination, that teaches or suggests the construction of a catheter balloon from a porous expanded PTFE.

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,



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